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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,067	12/13/2004	Carsten Pilger	MG-2519	2721

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CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,067	PILGER ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 and 8-14 have been cancelled. Claims 7 and 15-19 are under examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/07 has been entered.

Comment: Please amend the specification at the top of page 1 to reflect the continuing data and foreign applications priority data.

Terminal Disclaimer

The terminal disclaimer filed on 10/22/07 has been recorded.

Withdrawn rejections:

Claim 7 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of copending Application No. 10/517,722 and claim 7 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of copending Application No. 10/517,723 (Notice of allowability sent 1/25/07).

Applicant has amended instant claim 7 and filed a terminal disclaimer over 10/517,722 and the Examiner withdraws the rejection.

Claims 7 and 15-19 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant has amended the claims and the Examiner withdraws the rejection.

Claims 7 and 15-19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended the claims and the Examiner withdraws the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 recites the limitation "cerebral hemogenous medicament" in lines 13 and 19. There is insufficient antecedent basis for this limitation in the claim. In line 6, hemogenous has been deleted. The Examiner suggests deleting other references to hemogenous. Claims 15-19 are rejected as being indefinite because they are dependent on an indefinite base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7 and 15-19 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelt et al. (WO 00/53192) in view of Fishman (US 5,099,834) and Asahara et al. (Journal of Neurological Sciences 1999, 171, 84-87) and Alam et al. (Journal of Neurological Sciences 1998, 156, 102-106).

Applicant claims a method of treating a patient with a combination medicament comprising gaseous xenon and a cerebral medicament.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Petzelt et al. teach the use of xenon or xenon gas mixtures for neurointoxications, broadly including craniocerebral trauma, where the amount of xenon administered can be from 5 to 90% by volume or the more narrow range of 5 to 30 % by volume (Abstract; claims 1-13). Petzelt et al. teach inhalation methods (Page 8, third paragraph). Petzelt et al. teach disease states resulting from a neurotransmitter excess, particularly of glutamate, noradrenaline and/or dopamine (page 5, top). Thus, Petzelt et al. teach the instant patient population and inhalation of gaseous xenon mixtures in the instantly claimed amounts.

Fishman teach a method of anesthetizing a patient with a gas mixture consisting of from 60 to 78.5 mole percent stable xenon, from 19.5 to 38 mole percent oxygen and from 2.5 to 20.5 mole percent helium (Claim 1). Fishman teach use of the gas mixture in combination with intravenously introduced methyl-atrophine bromide, thiopentone and fentanyl (Column 5, lines 7-13). Fishman disclose a composition comprising 60-78.5 mol% xenon as well as the instant limit of 65 mol% (claims 1 and 2). Fishman broadly establish using the xenon gas mixture during surgery, which could as well be brain surgery (column 5, lines 6-7). Fishman teaches that the minimum amount of xenon required for anesthesia is 70-71% (column 2, lines 34-43). The Examiner notes that while Fishman teaches the MAC value of 70-71% xenon, Fishman claims the lower amount of 60% xenon in claim 1 and 65% xenon in claim 2 in the anesthetizing method. Fishman establish the use of xenon gas mixtures in combination with other medicaments such as the cerebral medicament thiopentone in surgery.

Alam et al. is relied upon for teaching that glutamate levels are elevated in migraine patients (page 104, 4. Discussion).

Asahara et al. is relied upon for teaching that glutamate levels are abnormally increased in amyotrophic lateral sclerosis (ALS) (Abstract).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

1. Petzelt et al. do not expressly teach co-administration of a cerebral medicament selected from a medicament for treating migraine, a medicament for the treatment of Alzheimer's disease, a medicament for the treatment of Huntington's disease, a medicament for the treatment of amyotropical lateral sclerosis and a medicament for the treatment of AIDS dementia.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to co-administer of a cerebral medicament to treat migraine or ALS in the method of Petzelt et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the Petzelt et al. teach the use of xenon gas mixtures for use in treating conditions characterized by excess neurotransmitters and the art teaches that both migraine and ALS are characterized by excess glutamate. This is a feature not observed with

Huntington's disease or Alzheimer's or AIDS dementia. Furthermore, the art, Fishman, teaches using xenon in combination with medicaments. Therefore the Examiner concludes that it would be obvious to treat a patient suffering from migraine or ALS with xenon and a medicament for migraine or ALS. Co-administration of medicaments specific for the treatment of these diseases is obvious. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

The determination of a specific volume of xenon from 5-60% or 5-50% or 5-40% or 5-30% or 5-20% volume is merely a matter of routine optimization of the amounts taught by Petzelt et al. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." And; "The results of ordinary innovation are not the subject of exclusive rights under the patent laws." KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. pgs. 12, 24; 550 U. S. ____ (2007)"

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserted that the conditions listed (migraine, Alzheimer's disease, Huntington's disease, ALS and AIDS dementia) are not caused by an increased release of neurotransmitters nor do these diseases lead to an increased release of neurotransmitters. Respectfully, the Examiner cannot agree. In researching the disease states, the Examiner has found that both migraine and ALS are characterized by increased glutamate, as shown above, and glutamate is a neurotransmitter specifically recited by Petzelt et al. thus rendering obvious diseases which are characterized by increased glutamate levels.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

Johann Richter
Supervisory Patent Examiner
Technology Center 1600